UNITED STATES DISTRICT COURT		
SOUTHERN DISTRICT OF NEW YOR		
	X	
MATTHEW MANN and	:	
MARAGARET MORRISSEY,	•	
MARAGARET MORRISSET,	•	08 CV 2061 (SCP)
Plaintiffs,	•	08-CV-2061 (SCR)
i idilitiis,	•	
VS.		
	:	
JAMES McCLUNG, M.D., ORANGE	:	
REGIONAL MEDICAL CENTER, DAV	OL:	
INC. and C.R. BARD, INC.,	:	
	:	
Defendants.	:	
	X	

ANSWER AND AFFIRMATIVE DEFENSES AND JURY DEMAND OF DEFENDANTS DAVOL INC. AND C.R. BARD, INC.

Defendants Davol Inc. ("Davol") and C.R. Bard, Inc. ("Bard"), (collectively, "Defendants") by and through counsel, answer the Plaintiffs' Complaint (the "Complaint") as follows:

AS AND FOR A FIRST CAUSE OF ACTION

- 1. The FIRST Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.
- 2. The SECOND Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.

- 3. The THIRD Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.
- 4. The FOURTH Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.
- 5. The FIFTH Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.
- 6. The SIXTH Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.
- 7. The SEVENTH Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.
- 8. The EIGHTH Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is

required, Defendants lack sufficient knowledge or information to form a belief as to the truth of

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the allegations in this paragraph and therefore deny the same.

- 9. The allegations in the NINTH Paragraph of the Complaint are not directed to Davol, and therefore no response is required. Bard admits that it is organized under the laws of the State of New Jersey and that it conducts business throughout the United States, including the State of New York. The remaining allegations in this paragraph are conclusions of law to which no answer is required. To the extent an answer is required, Bard accordingly denies the allegations.
- 10. The allegations in the TENTH Paragraph of the Complaint are not directed to Davol, and therefore no response is required. Bard states that the allegations in the TENTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Bard denies the allegations.
- 11. The allegations in the ELEVENTH Paragraph of the Complaint are not directed to Davol, and therefore no response is required. Bard states that the allegations in the ELEVENTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Bard denies the allegations.
- 12. The allegations in the TWELFTH Paragraph of the Complaint are not directed to Davol, and therefore no response is required. Bard admits that it conducts business throughout the United States, including the State of New York. Any remaining allegations in this paragraph contain conclusions of law to which no answer is required. To the extent an answer is required, Bard denies the allegations.
- 13. The allegations in the THIRTEENTH Paragraph of the Complaint are not directed to Davol, and therefore no response is required. Bard states that the allegations in the

THIRTEENTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Bard denies the allegations.

- 14. The allegations in the FOURTEENTH Paragraph of the Complaint are not directed to Bard, and therefore no response is required. Davol admits that it is organized under the laws of the State of Delaware with its principal place of business at 100 Sockanosset Crossroad, Cranston, Rhode Island. Davol further admits that it conducts business throughout the United States, including the State of New York. The remaining allegations in this paragraph are conclusions of law to which no answer is required. To the extent an answer is required, Davol denies the allegations.
- 15. The allegations in the FIFTEENTH Paragraph of the Complaint are not directed to Bard, and therefore no response is required. Davol states that the allegations in the FIFTEENTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Davol denies the allegations.
- 16. The allegations in the SIXTEENTH Paragraph of the Complaint are not directed to Bard, and therefore no response is required. Davol states that the allegations in the SIXTEENTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Davol denies the allegations.
- 17. The allegations in the SEVENTEENTH Paragraph of the Complaint are not directed to Bard, and therefore no response is required. Davol states that the allegations in the SEVENTEENTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Davol denies the allegations.
- 18. The allegations in the EIGHTEENTH Paragraph of the Complaint are not directed to Bard, and therefore no response is required. Davol states that the allegations in the

EIGHTEENTH Paragraph of the Complaint are conclusions of law, and no answer is required.

To the extent an answer is required, Davol denies the allegations.

- 19. The allegations in the NINETEENTH Paragraph of the Complaint are not directed to Bard, and therefore no response is required. Davol admits that it conducts business throughout the United States, including the State of New York. Any remaining allegations in this paragraph contain conclusions of law to which no answer is required. To the extent an answer is required, Davol denies the allegations.
- 20. The allegations in the TWENTIETH Paragraph of the Complaint are not directed to Bard, and therefore no response is required. Davol states that the allegations in the TWENTIETH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Davol denies the allegations.
- 21. Defendant Davol Inc. admits that it is a wholly owned subsidiary of Defendant C.R. Bard, Inc.
- 22. The allegations in the TWENTY-SECOND Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 23. The TWENTY-THIRD Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.
- 24. The TWENTY-FOURTH Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a

response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.

- 25. The TWENTY-FIFTH Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.
- 26. The TWENTY-SIXTH Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.
- 27. The TWENTY-SEVENTH Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.
- 28. The TWENTY-EIGHTH Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.
- 29. The TWENTY-NINTH Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.

- 30. The THIRTIETH Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.
- 31. The THIRTY-FIRST Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.
- 32. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and Defendants therefore deny the allegations.
- 33. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and Defendants therefore deny the allegations.
- 34. The allegations in the THIRTY-FOURTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 35. The allegations in the THIRTY-FIFTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

AS AND FOR A SECOND CAUSE OF ACTION **NEGLIGENCE**

36. In response to the THIRTY-SIXTH Paragraph of the Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.

- 37. The allegations in the THIRTY-SEVENTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 38. The allegations in the THIRTY-EIGHTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 39. The allegations in the THIRTY-NINTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 40. The allegations in the FORTIETH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 41. The allegations in the FORTY-FIRST Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 42. The allegations in the FORTY-SECOND Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 43. The allegations in the FORTY-THIRD Paragraph of the Complaint are either conclusions of law to which no answer is required or Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph. Accordingly, Defendants deny the allegations.

44. The allegations in the FORTY-FOURTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

AS AND FOR A THIRD CAUSE OF ACTION STRICT PRODUCT LIABILITY

- 45. In response to the FORTY-FIFTH Paragraph of the Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.
- 46. The allegations in the FORTY-SIXTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 47. The allegations in the FORTY-SEVENTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 48. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and Defendants therefore deny the allegations.
- 49. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and Defendants therefore deny the allegations.
- 50. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and Defendants therefore deny the allegations.
- 51. The allegations in the FIFTY-FIRST Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

52. The allegations in the FIFTY-SECOND Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

AS AND FOR A FOURTH CAUSE OF ACTION ON BEHALF OF THE PLAINTIFF, MATTHEW MANN BREACH OF WARRANTY

- 53. In response to the FIFTY-THIRD Paragraph of the Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.
- 54. The allegations in the FIFTY-FOURTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 55. The allegations in the FIFTY-FIFTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 56. The allegations in the FIFTY-SIXTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 57. The allegations in the FIFTY-SEVENTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 58. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and Defendants therefore deny the allegations.
- 59. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and Defendants therefore deny the allegations.

- 60. The allegations in the SIXTIETH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 61. The allegations in the SIXTY-FIRST Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 62. The allegations in the SIXTY-SECOND Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 63. The allegations in the SIXTY-THIRD Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 64. The allegations in the SIXTY-FOURTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

AS AND FOR A FIFTH CAUSE OF ACTION ON BEHALF OF THE PLAINTIFF, MARGARET MORRISSEY LOSS OF SERVICES

- 65. In response to the SIXTY-FIFTH Paragraph of the Complaint, Defendants incorporate by reference their responses in all preceding paragraphs.
- 66. The SIXTY-SIXTH Paragraph of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore deny the same.

- 67. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and Defendants therefore deny the allegations.
- 68. The allegations in the SIXTY-EIGHTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.
- 69. The allegations in the SIXTY-NINTH Paragraph of the Complaint are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

AFFIRMATIVE DEFENSES

- The Complaint, in whole or part, fails to state a claim or cause of action against 1. Defendants upon which relief can be granted.
- The doctrines contained in Restatement (Second) of Torts § 402A, Comment k, 2. bar Plaintiffs' claims against Defendants in whole or in part.
- 3. The doctrines contained in Restatement (Third) of Torts, Product Liability §§ 4 and 6, bar Plaintiffs' claims against Defendants in whole or in part.
- 4. The doctrine of spoliation and the failure to properly preserve evidence necessary to the determination of the alleged claims bars them.
- 5. Applicable statutes of limitations, statute of repose, and the doctrine of laches bar Plaintiffs' claims in whole or in part.
- 6. Plaintiffs', or Plaintiffs' agents', including Plaintiffs' physicians', misuse or abnormal use of the product or failure to follow instructions bar the Plaintiffs' claims in whole or in part.

- 7. If Plaintiffs used a product sold by Defendants, then Plaintiffs' claims are barred, in whole or in part, because Plaintiffs assumed the risks disclosed by the product labeling, by the prescribing physicians, or by other persons or entities.
- 8. Any alleged negligent or culpable conduct of Defendants, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of Plaintiffs' alleged injuries.
- 9. If Plaintiffs sustained any damages or injuries, then such damages and injuries were caused or contributed to by the acts, omissions or fault of Plaintiffs, including contributory negligence, contributory fault, comparative fault, assumption of the risk, or failure to mitigate damages.
- 10. If Plaintiffs used a product sold by Defendants, Plaintiffs used the product for offlabel purposes, which bars Plaintiffs' claims.
 - 11. The learned intermediary doctrine bars Plaintiffs' claims.
- 12. Plaintiffs' claims are barred, in whole or in part, because the products at issue were designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.
- 13. Plaintiffs' claims are barred, in whole or in part, because the products at issue were not defective or unreasonably dangerous in that they complied with, at all relevant times, all applicable government safety standards.
 - 14. Plaintiffs' claims are preempted, in whole or in part, by applicable federal law.
- 15. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs' injuries, if any, were the result of conduct of Plaintiffs, independent third parties, and/or events that were

extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to Plaintiffs' pre-existing medical conditions.

- If Plaintiffs suffered injury or damages as alleged, which is denied, such injury or 16. damage resulted from acts or omissions of persons or entities for which Defendants are neither liable nor responsible or resulted from diseases and/or causes that are not related or connected with any product sold, distributed, or manufactured by Defendants. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of Plaintiffs' alleged injury or damages.
- 17. Defendants state that if Plaintiffs sustained any damages or injuries, which is specifically denied, and such damages or injuries were caused by the acts, omissions or fault of Plaintiffs or others, for whose conduct this defendant is not responsible; accordingly, it is entitled to an assessment of the relative degree of fault for all such persons and entities.
- 18. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs' alleged injuries, if caused by the Bard® Ventralex® hernia repair patch, which is denied, were the result of Plaintiffs' own idiosyncratic reactions.
- 19. Plaintiffs failed to mitigate, which limits Plaintiffs' damages, if any, in whole or in part.
- 20. Defendants have no legal relationship or privity with Plaintiffs and owe no duty to Plaintiffs by which liability could be attributed to it.
- 21. Defendants made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiffs. If any such warranties were made, whether express or implied, which Defendants specifically deny, then Plaintiffs failed to give

notice of any breach thereof. Moreover, Defendants effectively and fully disclaimed any warranty, express or implied, in the sale of any product for which they are responsible in this matter.

- 22. Plaintiffs' causes of action are barred in whole or in part by Plaintiffs' own comparative negligence.
- 23. Plaintiffs' recovery, if any, shall be reduced by those payments that Plaintiffs received from collateral sources.
- If Plaintiffs have been injured or damaged, no injury or damages being admitted, 24. such injuries were not caused by Defendants' product.
- 25. At the time the product at issue, the Bard® Ventralex® hernia repair patch, left the custody and control of Defendants, there was no defect in said product that either caused or contributed to any injuries or damages that Plaintiffs may have suffered, if any.
- 26. The applicable state and federal law, including State Farm Mutual Auto. Ins. Co. v. Campbell, 538 U.S. 408 (2003), bars Plaintiffs' alleged claims for punitive or exemplary damages. Permitting recovery of punitive or exemplary damages in this case would violate Defendants' rights as reserved by the Fifth, Seventh, Eighth, and Fourteenth Amendments to the United States Constitution, and related provisions of the United States Constitution, as well as the applicable due process guarantees of the New York Constitution.
- 27. To the extent that the applicable state law permits the jury and Courts to measure punitive or exemplary damages by the net worth or financial status of Defendants and imposes greater punishment on defendants with greater net worth, such an award would be unconstitutional because it permits arbitrary punishment, allows bias and prejudice to infect the verdict, and allows dissimilar treatment of similarly situated defendants, all in violation of the

due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, and the similar provisions of the New York Constitution.

- 28. To the extent Plaintiffs' Complaint seeks punitive damages, such claims are barred because Plaintiffs have failed to allege conduct warranting the imposition of punitive damages under New York and/or other applicable laws.
- 29. To the extent Plaintiffs' Complaint seeks punitive damages, applicable federal law preempts any such claim, in whole or in part.
- 30. Plaintiffs' claims are, in whole or in part, subject to adjudication under the laws of states or jurisdictions other than New York.
- 31. Defendants hereby give notice that they intend to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves their right to amend this Answer to assert such defenses.

WHEREFORE, Defendants Davol Inc. and C.R. Bard, Inc. demand judgment in their favor and against Plaintiffs, dismissing Plaintiffs' Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

JURY TRIAL DEMAND

PLEASE TAKE NOTICE that answering Defendants hereby demand a trial by jury as to all issues.

Dated: March 7, 2008

Respectfully submitted,

PEPPER HAMILTON LLP

/s/ Samuel J. Abate, Jr. Samuel J. Abate, Jr. (SA 0915) Pepper Hamilton LLP The New York Times Building 620 Eighth Avenue New York, New York 10018-1405 212.808.2706 - direct 866.738.9621 - fax abates@pepperlaw.com

ATTORNEYS FOR DEFENDANT C.R. BARD, INC. AND DEFENDANT DAVOL INC.

CERTIFICATE OF SERVICE

I hereby certify that on March 7, 2008, a copy of the foregoing Answer and Affirmative Defenses and Jury Demand has been made upon the by first class mail:

> Jon C. Dupee, Jr., Esq. DUPEE & MONROE, P.C. P.O. Box 470 Goshen, NY 10924